

Ikuo Nishimoto
Appl. No. 10/088,699
Amdt. dated December 23, 2004
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group

PATENT

REMARKS/ARGUMENTS

Claims 2-19 are pending in the above-identified application. The specification has been amended to correct certain mistranslations in the original English translation of International Application No. PCT/JP00/06313, filed in Japanese. Further, claims 2, 8, 16, and 17 have been amended as set forth in detail below. Support for these amendments are identified in the following remarks. No new matter has been added. In view of the remarks and amendments set forth herein, examination and reconsideration of all pending claims are respectfully requested.

Interview Summary

Applicants thank the Examiner for the teleconference of December 15, 2004 with the undersigned, during which the outstanding issues in the instant case were discussed. It was agreed that certain amendments would be sufficient to obviate the rejections under 35 U.S.C. § 112, second paragraph. The present response serves to enter these amendments. No agreement regarding the other issues was reached during the interview.

Rejections under 35 U.S.C. §112, first paragraph

Claims 18 and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner believes that the referenced support for the limitation, "cross-hybridizing the nucleic acids to each other to identify non-redundant groups," at page 37, lines 8-24, to be insufficient descriptive support for cross-hybridization with respect to the identification of disorder suppressors for any condition, only with respect to Alzheimer's disease. Applicants respectfully traverse.

The written description requirement under 35 U.S.C. § 112, first paragraph, is met where the description provided in the specification conveys with reasonable clarity to one skilled in the art that, as of the effective filing date, the inventor had possession of the claimed invention. MPEP § 2163 (I) (citing *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ 1111, 1116 (Fed. Cir. 1991)). In the case of a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species. MPEP § 2163.05 (I), *Addition of Generic Claim*. A "representative number of species" means that the species that are adequately described are representative of the entire genus. *Id.* While more than one species may be necessary to describe a genus where there is substantial variation within the genus, a single species can be sufficient to support the genus where there is little or no variation with respect to the particular limitation at issue. *See id.* (citing cases). In particular, a single species will be sufficient to support a genus where the limitation at issue relates to subject matter well-known in the art and is "auxiliary" to the claimed invention. *See id.*, citing *In re Herschler*, 200 USPQ 711, 714 (CCPA 1979).

In view of the above standards, the disclosure in the specification of cross-hybridization of nucleic acids, with respect to the identification of disorder suppressors for Alzheimer's Disease, reasonably conveys to the skilled artisan possession of cross-hybridization with respect to the identification of disorder suppressors for any disorder. Cross-hybridization of nucleic acids is a technique that was well-known to the skilled artisan as of the effective filing date. Further, the cross-hybridization technique is auxiliary to the claimed invention, particularly since the technique is used to identify non-redundant groups of nucleic acids already identified by steps (a) to (c) as recited in independent claim 2. In this regard, Applicants note that, with respect to the application of this technique to identify non-redundant groups, the particular disorder is not critical and, therefore, the particular disorders encompassed within the generic claim do not impart variation with respect to the cross-hybridization limitation.

For the reasons set forth above, the skilled artisan reading the specification, including the cited disclosure of cross-hybridization in the context of Alzheimer's Disease, would

reasonably conclude that Applicants were in possession of a method of using of cross-hybridization with respect to identification of disorder suppressors of any disorder as presently recited in claims 18 and 19. Accordingly, the specification as filed provides written description for claims 18 and 19 under 35 U.S.C. § 112, first paragraph. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112, second paragraph

Claims 2, 4-8 and 10-19 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out an distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that the phrase "obtained from an organ affected by the disorder" render the claim indefinite because it is allegedly unclear what is encompassed with the limitation of an organ that is "affected by a disorder." Applicants respectfully traverse this rejection for the reasons set forth below.

While Applicants believe that the claims are definite under 35 U.S.C. § 112, second paragraph, but in order to further expedite prosecution of the instant application, independent claims 2 and 8 have been amended to recite that the "tissue is obtained from an organ showing cell death as a pathological feature of the disorder." Corresponding amendments have also been made to dependent claims 16 and 17. Support for these amendments is found throughout the specification, including, for example, at page 3, lines 14-17 and 21-24; and page 12, lines 2 and 3.

Per the discussion during the interview of December 15, 2004, claims 2 and 8 as amended obviate the instant rejection as allegedly indefinite under 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is respectfully requested.

Although the claim amendments as set forth above obviate the instant rejection, Applicants note that these amendments do not change the meaning of the claims as interpreted by the skilled artisan. A claim is definite under 35 U.S.C. § 112, second paragraph, where one of

skill in the art would understand the scope of the claim when the claim is read in light of the specification. *See North Am. Vaccine, Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993). In the present case, the specification refers to the phrase "affected area" as meaning "the area ... showing disorder-associated alterations or clinical symptoms" (Specification at page 11, lines 6-8.) Tissue alterations and clinical symptoms associated with a particular disorder are generally well-known to the skilled artisan. Further, such disease associated alterations or symptoms would not reasonably be understood by the skilled artisan as including death of all organs upon death of an organism suffering from a terminal disease, since disease processes are generally studied in the context of living organisms. For these reasons, Applicants submit that the skilled artisan reading the claims would understand the phrase "organ affected by the disorder" to mean an organ that shows one or more clinical symptoms or pathological features associated with the disorder. Accordingly, Applicants believe the claims as unamended are definite and, further, that the present amendments do not change or narrow the scope of the claims.

Rejections under 35 U.S.C. § 102

Claims 2, 4-8, and 10-17 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Giambarella *et al.* (*EMBO J.* 16:4897-4907, 1997). Claims 2, 4-8, and 10-17 also stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Guo *et al.* (*Proc. Natl. Acad. Sci. USA* 95:3227-3232, 1998). These rejections have been maintained from the previous Action. Essentially, the Examiner believes that the instant claims encompass embodiments in which the recited nucleic acid is obtained a tissue obtained from a normal organ, rather than a symptomatic organ. On this basis, the Examiner contends that the limitations of the instant claims are met by both the Giambarella and Guo references.

While Applicants do not agree with the Examiner's rejections nor reasons therefore, but in order to expedite prosecution of the instant application, the independent claims 2 and 8 now recite, *inter alia*, the following:

- (a) expressing in a cell a nucleic acid obtained from or synthesized from a nucleic acid obtained from a tissue of an organism suffering from a disorder ~~that accompanies cell death~~, wherein said tissue is obtained from an organ affected by showing cell death as a pathological feature of the disorder;

As previously set forth, this amendment finds support in the specification as filed at, for example, page 3, lines 14-17 ("... a disorder in which cell death is a pathological feature ..."); page 3, lines 21-24 ("[i]n disorders that accompany cell death, a pathological feature is the degeneration of cells in affected areas of organs or tissues in which cell death occurs"); and page 12, lines 2 and 3 ("... organs or tissues in which cell death occurs as the pathological feature of a disorder ...").

The specification clearly distinguishes between embodiments of the disclosed method in which an organ actually presents clinical symptoms and organs that have not yet developed clinical symptoms (*see, e.g.*, specification at page 8, lines 25-27, delineating between "organisms who show symptoms and those who have not yet developed visible clinical symptoms ... (emphasis provided)). Thus, the skilled artisan reading the claims as presently amended, in light of the specification, would understand that the phrase "showing cell death as a pathological feature of the disorder" delineates the recited organ from the broader interpretation for "organ affected by a disorder" as set forth by the Examiner. The specification further describes embodiments of the present invention in which tissue samples are obtained from organs that actually have clinical symptoms of a disorder, rather than just the potential for developing the disorder, at, *e.g.*, page 11, line 25, to page 12, line 12 (generally describing various embodiments of the invention in which samples are prepared from tissue obtained from organs having clinical symptoms of a disorder); and page 5, lines 6 and 7 (referring to one

specific embodiment in which RNA is prepared from brain tissue from a patient diagnosed with Alzheimer's disease).

Moreover, Applicants note that the claims as presently amended are clearly distinguishable over the cited art. Because the claims now recite an organ "showing cell death as a pathological feature of the disorder," embodiments in which tissue is taken from an organ that does not show pathological cell death are clearly excluded (*i.e.*, normal, non-symptomatic organs are explicitly not encompassed). The Examiner has not shown that the nucleic acids disclosed in the Giambarella and Guo references were obtained from tissue obtained from an organ showing cell death as a pathological feature of a disorder. The evidentiary references cited by the Examiner (Arriza *et al.*, *J. Neurosci.* 12:4045-4055, 1992, and Nordquist *et al.*, *J. Neurosci.* 8:4780-4789, 1988) do not disclose the tissue source for construction of the cDNA library as being obtained from an organ showing cell death as a pathological feature of a disorder. Further, even assuming, *arguendo*, that there may be any doubt as to the nature of the tissue from which the nucleic acids were derived, such doubt should inure to the benefit of the Applicants. *See In re Oetiker*, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (Plager, J., concurring) (stating that where the evidence is in "equipoise," an inventor is "entitled to a patent").

In view of the remarks and amendments set forth above, the claims as presently amended are novel over the cited art. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections of claims 2, 4-8, and 10-17 under 35 U.S.C. § 102(b).

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: December 23, 2004

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